

its quality system approved by the Associate Administrator. The quality system will initially be assessed through an audit by the Associate Administrator or his or her representative to determine whether it meets the requirements of this section. The Associate Administrator will notify the manufacturer in writing of the results of the audit. The notification will contain the conclusions of the audit and any corrective action required. The Associate Administrator may perform periodic audits to ensure that the manufacturer operates in accordance with the quality system. Reports of periodic audits will be provided to the manufacturer. The manufacturer must bear the cost of audits.

(2) *Quality system documentation.* The manufacturer must be able to demonstrate a documented quality system. Management must review the adequacy of the quality system to assure that it is effective and conforms to the requirements in § 178.70. The quality system records must be in English and must include detailed descriptions of the following:

- (i) The organizational structure and responsibilities of personnel with regard to design and product quality;
- (ii) The design control and design verification techniques, processes, and procedures used when designing the pressure receptacles;
- (iii) The relevant procedures for pressure receptacle manufacturing, quality control, quality assurance, and process operation instructions;
- (iv) Inspection and testing methodologies, measuring and testing equipment, and calibration data;
- (v) The process for meeting customer requirements;
- (vi) The process for document control and document revision;
- (vii) The system for controlling nonconforming material and records, including procedures for identification, segregation, and disposition;
- (viii) Production, processing and fabrication, including purchased components, in-process and final materials; and
- (ix) Training programs for relevant personnel.

(3) *Maintenance of quality system.* The manufacturer must maintain the qual-

ity system as approved by the Associate Administrator. The manufacturer shall notify the Associate Administrator of any intended changes to the approved quality system prior to making the change. The Associate Administrator will evaluate the proposed change to determine whether the amended quality system will satisfy the requirements. The Associate Administrator will notify the manufacturer of the findings.

(b) *Design type approvals.* The manufacturer must have each pressure receptacle design type reviewed by an IIA and approved by the Associate Administrator in accordance with § 178.70. A cylinder is considered to be of a new design, compared with an existing approved design, as stated in the applicable ISO design, construction and testing standard.

(c) *Production inspection and certification.* The manufacturer must ensure that each UN pressure receptacle is inspected and certified in accordance with § 178.71.

[71 FR 33885, June 12, 2006]

§ 178.70 Approval of UN pressure receptacles.

(a) *Initial design-type approval.* The manufacturer of a UN pressure receptacle must obtain an initial design type approval from the Associate Administrator. The initial design type approval must be of the pressure receptacle design as it is intended to be produced. The manufacturer must arrange for an IIA, approved by the Associate Administrator in accordance with subpart I of part 107 of this chapter, to perform a pre-audit of its pressure receptacle manufacturing operation prior to having an audit conducted by the Associate Administrator or his designee.

(b) *IIA pre-audit.* The manufacturer must submit an application for initial design type approval to the IIA for review. The IIA will examine the manufacturer's application for initial design type approval for completeness. An incomplete application will be returned to the manufacturer with an explanation. If an application is complete, the IIA will review all technical documentation, including drawings and calculations, to verify that the design

meets all requirements of the applicable UN pressure receptacle standard and specification requirements. If the technical documentation shows that the pressure receptacle prototype design conforms to the applicable standards and requirements in §178.70, the manufacturer will fabricate a prototype lot of pressure receptacles in conformance with the technical documentation representative of the design. The IIA will verify that the prototype lot conforms to the applicable requirements by selecting pressure receptacles and witnessing their testing. After prototype testing has been satisfactorily completed, showing the pressure receptacles fully conform to all applicable specification requirements, the certifying IIA must prepare a letter of recommendation and a design type approval certificate. The design type approval certificate must contain the name and address of the manufacturer and the IIA certifying the design type, the test results, chemical analyses, lot identification, and all other supporting data specified in the applicable ISO design, construction and testing standard. The IIA must provide the certificate and documentation to the manufacturer.

(c) *Application for initial design type approval.* If the pre-audit is found satisfactory by the IIA, the manufacturer will submit the letter of recommendation from the IIA and an application for design type approval to the Associate Administrator. An application for initial design type approval must be submitted for each manufacturing facility. The application must be in English and, at a minimum, contain the following information:

(1) The name and address of the manufacturing facility. If the application is submitted by an authorized representative on behalf of the manufacturer, the application must include the representative's name and address.

(2) The name and title of the individual responsible for the manufacturer's quality system, as required by §178.69.

(3) The designation of the pressure receptacle and the relevant pressure receptacle standard.

(4) Details of any refusal of approval of a similar application by a designated approval agency of another country.

(5) The name and address of the production IIA that will perform the functions prescribed in paragraph (e) of this section. The IIA must be approved in writing by the Associate Administrator in accordance with subpart I of part 107 of this chapter.

(6) Documentation on the manufacturing facility as specified in §178.69.

(7) Design specifications and manufacturing drawings, showing components and subassemblies if relevant, design calculations, and material specifications necessary to verify compliance with the applicable pressure receptacle design standard.

(8) Manufacturing procedures and any applicable standards that describe in detail the manufacturing processes and control.

(9) Design type approval test reports detailing the results of examinations and tests conducted in accordance with the relevant pressure receptacle standard, to include any additional data, such as suitability for underwater applications or compatibility with hydrogen embrittlement gases.

(d) *Modification of approved pressure receptacle design type.* Modification of an approved UN pressure receptacle design type is not authorized without the approval of the Associate Administrator. A manufacturer seeking modification of an approved UN pressure receptacle design type may be required to submit design qualification test data to the Associate Administrator before production. An audit may be required as part of the process to modify an approval.

(e) *Responsibilities of the production IIA.* The production IIA is responsible for ensuring that each pressure receptacle conforms to the design type approval. The production IIA must perform the following functions:

(1) Witness all inspections and tests specified in the UN pressure receptacle standard to ensure compliance with the standard and that the procedures adopted by the manufacturer meet the requirements of the standard;

(2) Verify that the production inspections were performed in accordance with this section;

(3) Select UN pressure receptacles from a prototype production lot and witness testing as required for the design type approval;

(4) Ensure that the various design type approval examinations and tests are performed accurately;

(5) Verify that each pressure receptacle is marked in accordance with the applicable requirements in § 178.72; and

(6) Furnish complete test reports to the manufacturer and upon request to the purchaser. The test reports and certificate of compliance must be retained by the IIA for at least 20 years from the original test date of the pressure receptacles.

(f) *Production inspection audit and certification.* (1) If the application, design drawing and quality control documents are found satisfactory, PHMSA will schedule an on-site audit of the pressure receptacle manufacturer's quality system, manufacturing processes, inspections, and test procedures.

(2) During the audit, the manufacturer will be required to produce pressure receptacles to the technical standards for which approval is sought.

(3) The production IIA must witness the required inspections and verifications on the pressure receptacles during the production run. The IIA selected by the manufacturer for production inspection and testing may be different from the IIA who performed the design type approval verifications.

(4) If the procedures and controls are deemed acceptable, test sample pressure receptacles will be selected at random from the production lot and sent to a laboratory designated by the Associate Administrator for verification testing.

(5) If the pressure receptacle test samples are found to conform to all the applicable requirements, the Associate Administrator will issue approvals to the manufacturer and the production IIA to authorize the manufacture of the pressure receptacles. The approved design type approval certificate will be returned to the manufacturer.

(6) Upon the receipt of the approved design type approval certificate from the Associate Administrator, the pressure receptacle manufacturer must sign the certificate.

(g) *Recordkeeping.* The production IIA and the manufacturer must retain a copy of the design type approval certificate and certificate of compliance records for at least 20 years.

(h) *Denial of design type application.* If the design type application is denied, the Associate Administrator will notify the applicant in writing and provide the reason for the denial. The manufacturer may request that the Associate Administrator reconsider the decision. The application request must—

(1) Be written in English and filed within 60 days of receipt of the decision;

(2) State in detail any alleged errors of fact and law; and

(3) Enclose any additional information needed to support the request to reconsider.

(i) *Appeal.* (1) A manufacturer whose reconsideration request is denied may appeal to the PHMSA Administrator. The appeal must—

(i) Be written in English and filed within 60 days of receipt of the Associate Administrator's decision on reconsideration;

(ii) State in detail any alleged errors of fact and law;

(iii) Enclose any additional information needed to support the appeal; and

(iv) State in detail the modification of the final decision sought.

(2) The PHMSA Administrator will grant or deny the relief and inform the appellant in writing of the decision. PHMSA Administrator's decision is the final administrative action.

(j) *Termination of a design type approval certificate.* (1) The Associate Administrator may terminate an approval certificate issue under this section if it is determined that, because of a change in circumstances, the approval no longer is needed or no longer would be granted if applied for; information upon which the approval was based is fraudulent or substantially erroneous; or termination of the approval is necessary to adequately protect against risks to life and property.

(2) Before an approval is terminated, the Associate Administrator will provide the manufacturer and the approval agency—

(i) Written notice of the facts or conduct believed to warrant the withdrawal;

(ii) Opportunity to submit oral and written evidence, and

(iii) Opportunity to demonstrate or achieve compliance with the application requirement.

(3) If the Associate Administrator determines that a certificate of approval must be withdrawn to preclude a significant and imminent adverse affect on public safety, the procedures in paragraph (j)(2)(ii) and (iii) of this section need not be provided prior to withdrawal of the approval, but shall be provided as soon as practicable thereafter.

[71 FR 33886, June 12, 2006, as amended at 71 FR 54397, Sept. 14, 2006]

§ 178.71 Specifications for UN pressure receptacles.

(a) *General.* Each UN pressure receptacle must meet the requirements of this section. Requirements for approval, qualification, maintenance, and testing are contained in § 178.70, and subpart C of part 180 of this subchapter.

(b) *Definitions.* The following definitions apply for the purposes of design and construction of UN pressure receptacles under this subpart:

Alternative arrangement means an approval granted by the Associate Administrator for a MEGC that has been designed, constructed or tested to the technical requirements or testing methods other than those specified for UN pressure receptacles in part 178 or part 180 of this subchapter.

Bundle of cylinders. See § 171.8 of this subchapter.

Design type means a pressure receptacle design as specified by a particular pressure receptacle standard.

Design type approval means an overall approval of the manufacturer's quality system and design type of each pressure receptacle to be produced within the manufacturer's facility.

UN tube. See § 171.8 of this subchapter.

(c) *General design and construction.* UN pressure receptacles and their closures must be designed, manufactured, tested and equipped in accordance with the requirements contained in this section.

(1) Following the final heat treatment, all cylinders, except those selected for batch testing must be subjected to a hydraulic volumetric expansion test.

(2) The standard requirements applicable to UN pressure receptacles may be varied only if approved in writing by the Associate Administrator.

(3) The test pressure of UN cylinders, tubes, and bundles of cylinders must conform to the requirements in part 178 of this subchapter.

(d) *Service equipment.* (1) Except for pressure relief devices, UN pressure receptacle equipment, including valves, piping, fittings, and other equipment subjected to pressure must be designed and constructed to withstand at least 1.5 times the test pressure of the pressure receptacle.

(2) Service equipment must be configured or designed to prevent damage that could result in the release of the pressure receptacle contents during normal conditions of handling and transport. Manifold piping leading to shut-off valves must be sufficiently flexible to protect the valves and the piping from shearing or releasing the pressure receptacle contents. The filling and discharge valves and any protective caps must be secured against unintended opening. The valves must conform to ISO 10297 (IBR, see § 171.7 of this subchapter) and be protected as specified in § 173.301b(f) of this subchapter.

(3) UN pressure receptacles that cannot be handled manually or rolled, must be equipped with devices (e.g. skids, rings, straps) ensuring that they can be safely handled by mechanical means and so arranged as not to impair the strength of, nor cause undue stresses, in the pressure receptacle.

(4) Pressure receptacles filled by volume must be equipped with a level indicator.

(e) *Bundles of cylinders.* UN pressure receptacles assembled in bundles must be structurally supported and held together as a unit and secured in a manner that prevents movement in relation to the structural assembly and movement that would result in the concentration of harmful local stresses. The frame design must ensure